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Comments

INNOCUOUS INOCULUM OR PERILOUS PARASITE? ENCOURAGING GENETIC RESEARCH THROUGH PATENT GRANTS: A CALL FOR REGULATION AND DEBATE

This Comment examines the effect of the United States Supreme Court's Diamond v. Chakrabarty decision on research in recombinant genetics. Although the Supreme Court has recited its inability to deny patents for microorganisms, the Comment suggests several grounds for refusing to extend patent protection to products of genetic research; not least among which is the danger such research poses to public health, morals, and well-being. Concluding that the Supreme Court's decision will encourage genetic research that is not currently subject to government safety guidelines, the Comment calls for congressional action to govern such research and suggests several regulatory schemes.

INTRODUCTION

The Constitution authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."¹ Accordingly, since 1790, Congress has enacted a number of Patent Acts.² The 1952 Act³ gives the patent

1. U.S. CONST. art. I, § 8, cl. 8. This clause has been interpreted to grant Congress the authority to establish a patent system. See Note, *Ownership of Living Inventions*—In re Bergy, 29 DE PAUL L. REV. 215, 215 n.2 (1979).

2. For a discussion of patent acts from the earliest act of April 10, 1790, to the

holder a seventeen year monopoly, enabling the holder to prevent others from making, using or selling the invention.⁴

The primary purpose of the patent system has been stated to be the encouragement of technological advancement,⁵ rather than reward to the individual inventor.⁶ The system is foremost a device that serves the public by promoting inventions that benefit society in a tangible way. The system is not intended to promote "pure science" in and of itself, but only those "useful Arts" of practical value to the public.⁷ This excludes inventions which are "frivolous or injurious to the well-being, good policy, or morals of society."⁸

In *Diamond v. Chakrabarty*,⁹ the United States Supreme Court recognized genetic research potentially poses serious threats to society.¹⁰ Nevertheless, the Court refused to consider these dangers. Reasoning that the denial of patents for microorganisms is not likely to stop genetic research, the Court passed to Congress the burden of evaluating the competing values and interests involved in encouraging such research.¹¹ Part I of this Comment examines the basis of the Supreme Court's decision. Part II discusses the propriety of extending patent grants for products of genetic research before establishing a regulatory system for such

last major act of 1952 see 1 A. DELLER, *DELLER'S WALKER ON PATENTS* 85-100 (2d ed. 1964).

3. Act of July 19, 1952, ch. 950, 66 Stat. 792 (codified at 35 U.S.C. §§ 1-376 (1976)).

4. 35 U.S.C. § 154 (1976).

5. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330-31 (1945). "The constitutionally stated purpose for enacting the patent system is the promotion of progress in the 'useful Arts' rather than in 'Science'. This was the conclusion of both houses of Congress in enacting the 1952 Patent Act The term 'useful Arts' now refers to 'technological arts.'" Note, *Ownership of Living Inventions—In re Bergy*, 29 DE PAUL L. REV. 215, 215 n.2 (1979).

6. The scope of the patent claim has reached beyond what a reward to the individual would require. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

7. *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358 (7th Cir. 1907). The patent system is an incentive system that operates primarily on business men and secondarily on inventors to encourage the supply of new devices useful to the public. Dienger, *Patents for Biological Specimens and Products*, 35 J. PAT. OFF. SOC'Y 286 (1953). Congress balanced the economic interests of the inventor with public interests in designing the patent statutes. Note, *The Patentability of Living Matter: Hey Waiter, What's Chakrabarty's Pseudomonas Bacterium Doing Back in the Supreme Court's Soup?*, 37 WASH. & LEE L. REV. 183 (1980).

8. Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: In re Bergy, 58 NEB. L. REV. 303, 305 (1978) (quoting *Lowell v. Lewis*, 15 F.Cas. 1018 (C.C.Mass. 1817) (No. 8,568)).

9. 100 S. Ct. 2204 (1980).

10. 100 S. Ct. at 2211.

11. 100 S. Ct. at 2211-12.

research and without the opportunity for public debate. Part III suggests possible congressional action to resolve any conflicting interests or policies.

THE FRAMEWORK

Statutory Limitations on Patentability

The subject matter for which a patent may be obtained is defined in 35 U.S.C. § 101.¹² Because patents deal with inventions, which are by nature things previously unknown, the classes of patentable subject matter in section 101 were defined in very broad and general terms.¹³ Broad statutory requirements of "utility" and "statutory subject matter" are set out in section 101.¹⁴ A novelty determination is made under section 102.¹⁵ Section 103 codifies a judicially created nonobviousness limitation.¹⁶

12. 35 U.S.C. § 101 (1976) provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

13. These statutory vagaries are occasionally a source of controversy, especially when, as in *Chakrabarty*, the Patent and Trademark Office (PTO) must determine for the first time that an invention constitutes statutory subject matter under § 101.

14. This section has been interpreted as stating three requirements for patentability: novelty, utility, and statutory subject matter. See Note, *Ownership of Living Inventions*—In re Bergy, 29 DE PAUL L. REV. 218 (1979). But see note 15 *infra*.

15. 35 U.S.C. § 102 (1976). The PTO has consistently applied § 102 in making rejections for lack of novelty. *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979). In only two cases has the novelty rejection been made under § 101. See *In re Bergstrom*, 427 F.2d 1394 (C.C.P.A. 1970); *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964). The inventor or discoveror must be the first to invent or discover the subject of the patent claim in substantially the same manner as it was invented. This determination requires a comparison with the "prior art." "Prior art" is "[a]nything in tangible form that may properly be relied on by the Patent Office under the Patent Statutes and the Patent Office Rules of Practice in Patent Cases in support of rejection on matter of substance, not form, of a claim in a pending application for patent." 5 A. DELLER, DELLER'S WALKER ON PATENTS 361 (2d ed. 1964) (emphasis in original). The determination of "prior art" by the courts is sometimes quite arbitrary. See note 75 and accompanying text *infra*.

16. 35 U.S.C. § 103 (1976). "Section 103 is a restatement of the rule invalidating patents for lack of invention or lack of patentable novelty which has long been recognized by the courts and other authorities but [had] not before been spelled out in the statute." Zinn, *Commentary on New Title 35, U.S. Code "Patents"*, U.S. CODE CONG. & AD. NEWS 2507, 2513 (1952). Under § 103, a patent will be allowed only "if the difference between the subject matter sought to be patented and the prior art [is] such that the subject matter as a whole [would not] have been obvious at the time the invention was made to a person ordinarily skilled in the art." 35 U.S.C. § 103 (1976).

Section 112 of the Patent Act is particularly important in determining the patentability of living matter.¹⁷ That section requires a written description of the subject matter of the patent sufficiently detailed to enable one skilled in the art to make and use the invention.

Judicially Created Limitations on Patentability

The patent statutes' requirements do not provide the only limitations on patentability. While the courts have broadly construed the possible classes of patentable subject matter, they have also delineated certain subjects that fall outside the purview of patent coverage. For example, the subject of a patent claim is not patentable where its novelty consists merely of an arrangement of printed matter,¹⁸ a phenomenon of nature,¹⁹ methods of doing business,²⁰ mental steps,²¹ or mathematical formulae or algorithms.²²

One frequently stated judicially created²³ limitation is that a "product of nature" cannot be patented.²⁴ This "product of nature" doctrine dates back at least to 1889.²⁵ For seventy-five years or more the doctrine was invoked by both the Patent and Trade-

17. 35 U.S.C. § 112 (1980) provides in pertinent part:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The application of this section to living organisms has been the matter of some controversy. See notes 110-11 and accompanying text *infra*.

18. *Conover v. Coe*, 99 F.2d 377 (D.C. Cir. 1938).

19. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853).

20. *In re Chatfield*, 545 F.2d 152, 157 (C.C.P.A. 1976), *cert. denied*, 434 U.S. 875 (1977).

21. *In re Benson*, 441 F.2d 682 (C.C.P.A. 1971), *rev'd sub nom.* *Gottschalk v. Benson*, 409 U.S. 63 (1972).

22. *In re Flook*, 559 F.2d 21 (C.C.P.A. 1977), *rev'd sub nom.* *Parker v. Flook*, 437 U.S. 584 (1978).

23. See Note, *Living Matter Found to be Patentable: In re Chakrabarty*, 11 CONN. L. REV. 311 (1979); Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101: In re Bergy*, 58 NEB. L. REV. 303, 307 (1978).

24. A "product of nature" has been variously defined as "a naturally occurring element, composition of matter or substance that can be found in and extracted from minerals or living organisms." Gutttag, *The Patentability of Microorganisms: Statutory Subject Matter and Other Living Things*, 13 U. RICH. L. REV. 247, 252 n.27 (1979), and as "one occurring on the earth in a form that has not been changed by any act of a human being." 47 MICH. L. REV. 391, 395 (1949).

25. See *Ex parte Latimer*, 46 Off. Gaz. Pat. Office 1638 (1889).

mark Office (PTO) and the courts to invalidate various patent claims without reference to specific statutory authority.²⁶

A second, distinct, judicially created limitation is the "phenomenon of nature" doctrine.²⁷ In order for an invention which embodies a phenomenon of nature to be patentable, its development must have required more than the ordinary skill of a person in the art or profession, given the state of the "prior art" when the subject matter was developed.²⁸ Fundamental to the doctrine is the principle that the phenomena are neither "inventions" nor "discoveries" as defined by the Patent Act.²⁹ All phenomena of nature, even if newly discovered, are treated as well-known aspects of the "prior art." Therefore, the phenomenon of nature doctrine precludes from patentability the phenomenon itself together with its fundamental applications.³⁰

One commentator has noted that the courts have used the

26. See Behringer, *Germ Warfare in the Patent Courts?*, 31 HASTINGS L.J. 883, 895 n.86 (1980). The doctrine was first assumed to be an interpretation of § 101: that products of nature were not "new" and therefore not patentable subject matter under the section. See, e.g., *Ex parte Siddiqui*, 156 U.S.P.Q. (BNA) 426 (PTO Bd. App. 1966); Jacob, *Patentability of Natural Products*, 52 J. PAT. OFF. SOC'Y 473 (1970). The C.C.P.A. rejected that analysis, contending that the product of nature doctrine was an expression of the novelty requirements of § 102. See Behringer, *supra*, at 896.

While certain decisions have professed to rely on the C.C.P.A.'s analysis, consideration of the facts suggest that the actual basis of the holdings lay elsewhere. Guttag, *supra* note 24, at 252. In view of the difficulties in applying the product of nature doctrine, some courts have rejected it, *id.* at 253; see, e.g., *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156 (4th Cir. 1958), *rev'g*, 152 F. Supp. 690 (W.D. Va. 1957); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912), while others have attempted to establish a distinction based on purification of the naturally occurring material. See Guttag, *supra* note 24, at 254-55 for a discussion of the failure of the courts to reconcile the "product of nature" doctrine with the "purification of naturally occurring substance" treatments.

In recent cases, the C.C.P.A. has left open the question of whether a product of nature rejection is proper when the claimed material existed unrecognized in nature. See, e.g., *In re Kratz*, 201 U.S.P.Q. (BNA) 71 (C.C.P.A. 1979). The court noted that support for such a rejection can be found only in dicta, *id.* at 75, but held that "products of nature" may be patentable when the other requirements for patentability are met. See generally Note, *Living Matter Found to be Patentable*: In re Chakrabarty, 11 CONN. L. REV. 311, 318-19 (1979).

27. Note, *supra* note 7, at 185-86. Exactly what constitutes a "phenomenon of nature" is unclear. See note 33 *infra*.

28. See, e.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948); *Armour Pharm. Co. v. Richardson-Merrell Inc.*, 396 F.2d 70, 74 (3d Cir. 1968).

29. See, e.g., *Parker v. Flook*, 437 U.S. 584, 593 (1978).

30. Note, *supra* note 7, at 187.

terms "phenomenon of nature," "laws of nature," "principles of nature," and "fundamental truths" synonymously.³¹ All of these terms are poorly defined. They are "vague and malleable terms infected with too much ambiguity and equivocation."³² Such ambiguity allows the courts great discretion in the application of the doctrine,³³ and its use or rejection has at times been arbitrary or unexplained.³⁴

Despite the great discretion exercised by the courts in applying judicially created limitations, the courts have claimed that they do not expand the law; they merely interpret the congressional intent underlying the patent statute.³⁵ One commentator has disputed this claim.³⁶ He concludes that in determining patentable subject matter, the Court of Customs and Patent Appeals (C.C.P.A.) has tried to expand the scope of section 101 by "judicial fiat,"³⁷ not by statutory interpretation.

Microorganism Patent Claims in the Courts

The courts use a two-step analysis in affording patent protection to microorganisms; (1) the patent statutes allow patents for

31. *Id.* at 188 n.31.

32. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 135 (1948) (Frankfurter, J., concurring).

33. The doctrine has been applied to exclude patents embodying the following: physical laws of nature, such as gravity, (*but see* *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923) (A machine with one end elevated was held to embody a phenomenon of nature. *Id.* at 52. The machine was held patentable. *Id.* at 69-70. Later courts have recognized that the use of the phenomenon was inventive. *See, e.g.*, *Parker v. Flook*, 437 U.S. at 590)); physical properties of nature, such as heat of the sun and electricity, (*see* *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. at 130) (recognizing that heat of the sun and electricity are phenomena of nature); "inherent physical properties of naturally occurring animate and inanimate matter," (*id.* noninhibitive properties in strains of bacteria held phenomenon of nature); *Le Roy v. Tatham*, 55 U.S. (14 How.) 155, 175-76 (1852) (properties of lead). The scope of this class of phenomena is not well defined due to the imprecise definition of the term "inherent properties." Previous decisions concerning this class of phenomena indicate that it includes properties exhibited only under conditions not found in nature. *See, e.g.*, *Davison Chem. Corp. v. Joliet Chems., Inc.*, 179 F.2d 793, 795 (7th Cir. 1950) (property demonstrated only at extremely high temperatures); *In re Arnold*, 185 F.2d 686, 691 (C.C.P.A. 1950) (property demonstrated only when molecules subjected to extremely high frequency electricity)); and mathematical equations and methods of calculation, (*see* *Parker v. Flook*, 437 U.S. at 595 n.18). Note, *supra* note 7, at 188-89.

34. *See, e.g., In re Bergy*, 596 F.2d 952, 965 (C.C.P.A. 1979). The *Bergy* majority held that the claim for a biologically pure culture of a bacterium found in nature did not involve phenomena of nature, thereby making the doctrine inapplicable. The court failed to give any explanation to support its determination.

35. This is based on the courts' duty to decide cases of first impression through an exercise of discretion in interpreting the statute. *Id.* at 984-87.

36. Note, *Patenting the Microorganism: In re Bergy, The First Step up the Chain of Life*, 2 GEO. MASON U.L. REV. 265, 276 (1978).

37. *Id.* at 277-78.

claims to processes using microorganisms³⁸ and to compositions containing microorganisms in admixture with inanimate matter,³⁹ and (2) the patent statutes do not expressly bar microorganism patents.⁴⁰ This analysis has been challenged on the grounds that there is a distinction between processes using living organisms or inoculums containing living organisms and the living organisms alone,⁴¹ and that the Plant Patent Act of 1930⁴² and the Plant Variety Protection Act of 1970⁴³ indicate that no living organism is patentable outside of their provisions.⁴⁴ These basic lines of reasoning were followed by the lower courts deciding *In re*

38. See, e.g., *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453, 462-63 (2d Cir.), *cert. denied*, 209 U.S. 548 (1908); *Ex parte Prescott*, 19 U.S.P.Q. (BNA) 178 (PTO Bd. App. 1932).

39. U.S. PATENT AND TRADEMARK OFFICE, *MANUAL OF CLASSIFICATION* 424-1 (1979) (Class 71, subclass 6 (fertilizer compositions containing bacteria); Class 195, subclass 59 (fermentation products containing live bacteria); Class 424, subclass 93 (drugs containing whole live bacteria)).

40. Gutttag, *supra* note 24.

41. See, e.g., *Guaranty Trust Co. of New York v. Union Solvents Corp.*, 54 F.2d 400 (D. Del. 1931), *aff'd per curiam*, 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933). In upholding the patent of the Weizmann process for the production of acetone and butyl alcohol by bacterial fermentation the court made the following observation in dicta:

Lastly, the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the life process of a living organism. Were the patent for bacteria per se, a different situation would be presented. As before stated, the patent is not for bacteria per se. It is for a fermentation process employing bacteria . . .

54 F.2d at 410. Cf. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). (The *Kalo* Court simply assumed that a mixed inoculant of non-inhibitive strains of bacteria constituted statutory subject matter. The Court's decision to grant the patent was based on the ground that the mixed inoculant was a "patentable advance" within the meaning of the statute.) Gutttag, *supra* note 24, at 261.

42. 35 U.S.C. §§ 161-164 (1976).

43. 7 U.S.C. §§ 2321-2583 (1976).

44. At least one court has assumed, in dictum, that plants were not within the patent laws until the Plant Patent Act was enacted. *Yoder Bros. Inc. v. California—Florida Plant Corp.*, 537 F.2d 1347, 1377 (5th Cir. 1976), *cert. denied*, 429 U.S. 1094 (1977). The best argument for the proposition that plants (or any other living organisms) were not patentable prior to 1930 can be found in a transitory provision which precluded patent protection for plants prior to May 23, 1930. Plant Patent Act of 1930, ch. 312, § 5, 46 Stat. 376. It has been argued that the restrictive terms of the Plant Patent Act, allowing patent protection only for asexually reproducing plants, indicate that Congress intended the Act to be exclusive of other plants and other organisms. Note, *Patenting the Microorganism: In re Bergy, The First Step up the Chain of Life*, 2 GEO. MASON U.L. REV. 265, 272 (1978), and that, had living matter been otherwise patentable, the Plant Patent Act would have been unnecessary. See, e.g., *In re Bergy*, 596 F.2d 952, 999 (C.C.P.A. 1979) (Miller, J., dissenting). The 1970 Act extended patent protection for certain sexually producing plant varieties. 7 U.S.C. §§ 2321-2583 (1976).

*Bergy*⁴⁵ and *In re Chakrabarty*,⁴⁶ the two cases preceding the Supreme Court's decision in *Diamond v. Chakrabarty*.⁴⁷

Dr. Ananda Chakrabarty, a microbiologist working for the General Electric Company,⁴⁸ genetically engineered a new strain of bacteria of the genus *Pseudomonas* capable of degrading several hydrocarbon components of crude oil.⁴⁹ Chakrabarty's patent application contained thirty-six claims, divisible into four groups.⁵⁰ The Patent Office Examiner allowed the two groups that claimed a process incorporating the bacteria.⁵¹ He rejected, however, the two groups directed at the bacterium itself, or at an inoculum consisting essentially of the bacteria,⁵² on the ground that they claimed a nonpatentable product of nature.⁵³

45. *Ex parte Bergy*, 197 U.S.P.Q. (BNA) 78 (PTO Bd. App. 1976), *rev'd sub nom. In re Bergy*, 563 F.2d 1031 (C.C.P.A. 1977), *vacated and remanded*, 438 U.S. 902 (1978), *aff'd*, 596 F.2d 952 (C.C.P.A.), *cert. granted*, 444 U.S. 924 (1979), *vacated as moot*, 444 U.S. 1028 (1980).

46. *In re Chakrabarty*, 571 F.2d 40 (C.C.P.A. 1978), *cert. dismissed sub nom. Banner v. Chakrabarty*, 439 U.S. 801 (1978), *aff'd on rehearing sub nom. In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *aff'd sub nom. Diamond v. Chakrabarty*, 100 S. Ct. 2204 (1980).

47. *Diamond v. Chakrabarty*, 100 S. Ct. 2204 (1980).

48. General Electric was the real party in interest as the assignee of Dr. Chakrabarty's interest in the patent application. *In re Bergy*, 596 F.2d 952, 956 (C.C.P.A. 1979).

49. *In re Chakrabarty*, 571 F.2d 40, 41-43 (C.C.P.A. 1978). The new strain of microorganism was created by transmitting four plasmids into an existing strain of *Pseudomonas aeruginosa*. While the existing strains had limited ability to degrade crude oil components, each of the four transmitted plasmids contained degradative pathways capable of converting the oil to a normal food substance of the bacterium in which they were placed, thus making the new organism capable of digesting various oil components. The microorganisms have valuable potential for cleaning-up oil spills. *In re Bergy*, 596 F.2d at 969; Cripps, *Genetic Engineering—A Problem For the Patent Office?*, 1979 NEW ZEALAND L.J. 232, 233.

For an explanation of the "gene splicing" process used by Dr. Chakrabarty see Baker & Clough, *The Technological Uses and Methodology of Recombinant DNA*, 51 S. CAL. L. REV. 1009 (1978).

One commentator has suggested that, "[l]ike Dr. Frankenstein, Dr. Chakrabarty created a living thing." Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: *Parker v. Bergy* (*Parker v. Chakrabarty*), 15 NEW ENG. L. REV. 379, 392 (1980). This is clearly mistaken. Dr. Chakrabarty did not instill life into inanimate matter, he merely transferred certain "organic" structures into an already living organism. The issue in the case is not properly the patentability of "life" or "aliveness," but the patentability of a novel, genetically developed species. See Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: *In re Bergy*, 91 HARV. L. REV. 1357, 1361-62 (1978).

50. *In re Bergy*, 596 F.2d 952, 970 (C.C.P.A. 1979).

51. Claims 27, 28, and 29 comprised a group directed at a process, or improvement in a process, of transferring plasmids from a donor to a recipient bacterium. *Id.* Claims 30, 31, 32, 35, and 36 comprised a group directed at an inoculated medium constituting a carrier material able to float on water (straw). *Id.* at 970-71.

52. The claims for the bacterium were Claims 7, 8, 9, 13, 15, 17, and 21. *Id.* Those for the inoculum were Claims 21, 24, 25, and 26. *Id.* at 970.

53. *Id.* at 971.

On appeal, the PTO Board of Appeals erroneously interpreted the Examiner's rejection as stating two grounds for nonpatentability of the latter two groups of claims:⁵⁴ that the organism was a product of nature and that the organism was a living thing. The Board reversed the Examiner on the first ground,⁵⁵ but upheld the rejection on the second ground, reasoning that the Plant Patent Act excluded living organisms as patentable subject matter.⁵⁶

The Court of Customs and Patent Appeals (C.C.P.A.) reversed the Board and held that neither case law nor statutes could be interpreted to exclude living organisms from patentability under section 101.⁵⁷ Chief Judge Markey, speaking for the C.C.P.A., observed: "No Congressional intent to limit patents to dead [sic] inventions lurks in the lacuna of the statute, and there is no grave or compelling circumstance requiring us to find it there."⁵⁸ Judge Markey reasoned that the modified bacteria fell within the meaning of the terms "manufacture" or "composition of matter." He argued that there are but two sources of manufactures and compositions of matter: nature and man. Because the organism was a "manufacture" of man, Judge Markey concluded that it was within the statutory subject matter and to find otherwise would "defeat the fundamental purpose of the Constitution and of the Patent laws enacted thereunder."⁵⁹ While the PTO was appealing the C.C.P.A.'s *Chakrabarty* decision, the Supreme Court remanded the *Bergy* case to the C.C.P.A. for rehearing in light of *Parker v. Flook*.⁶⁰

In Light of Parker v. Flook

In *Flook* the applicant sought a patent for a method of updating

54. Note, *Ownership of Living Inventions*—In re Bergy, 29 DE PAUL L. REV. 215, 222 (1979).

55. This ground, while justifiable in *Bergy*, was clearly inapplicable in this case as *Chakrabarty*'s strain of the *Pseudomonas* bacterium presumably does not exist undiscovered in nature. The Board used analysis similar to that used in *Bergy* to conclude that the product of nature doctrine was inapplicable. In re *Chakrabarty*, 571 F.2d at 42.

56. *Id.* at 42.

57. *Id.* at 43.

58. *Id.* at 44.

59. *Id.*

60. 437 U.S. 584 (1978). Because *Bergy* and *Chakrabarty* both involved a determination of the patentability of a microorganism the C.C.P.A. vacated its *Chakrabarty* decision and consolidated the two cases for reargument. In re *Bergy*, 596 F.2d at 957.

alarm limits during catalytic conversion processes. The patent claims rested on a mathematical formula or algorithm.⁶¹ The Supreme Court rejected the patent claims, based on its earlier decision in *Gottschalk v. Benson*,⁶² that novel and useful mathematical formulae are merely ideas, and that ideas are not patentable subject matter.⁶³

In a frequently cited passage,⁶⁴ the *Flook* Court argued in favor of judicial restraint and narrow construction of the patent statutes and case law.⁶⁵ The language of that passage and the Court's action in summarily vacating and remanding *Bergy* for reconsideration in light of *Flook* seem to show some reluctance to extend patent protection to new technologies.⁶⁶ Unfortunately, the Court issued no clear directives indicating what bearing *Flook* had on *Bergy*.⁶⁷

The C.C.P.A., considering *Bergy* on remand with *Chakrabarty*, decided the only thing the two cases had in common with *Flook* was that they all involved section 101.⁶⁸ This is an overly narrow reading of the *Flook* opinion. It was a matter of some concern and confusion for the *Flook* Court that the applicant did not seek to patent the algorithm, but only one limited application of it.⁶⁹ The Court stated that it is "clear that a process is not unpatent-

61. *Parker v. Flook*, 437 U.S. 584, 584 (1978).

62. 409 U.S. 63 (1972).

63. *Id.* at 72.

64. 437 U.S. at 596. See, e.g., Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101: Parker v. Bergy (Parker v. Chakrabarty)*, 15 NEW ENG. L. REV. 379, 390 (1980).

65. The Court said:

It is our duty to construe the patent statutes as they now read, in light of our prior precedents, and we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress.

....

[W]e should not expand patent rights by overruling or modifying our prior cases construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language. We would require a clear and certain signal from Congress . . .

437 U.S. at 596 (quoting *Deepsouth Packing Co. Inc. v. Laitram Corp.*, 406 U.S. 518, 531 (1972)).

66. Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101: Parker v. Bergy (Parker v. Chakrabarty)*, 15 NEW ENG. L. REV. 379, 389 (1980).

67. Note, *Ownership of Living Inventions—In re Bergy*, 29 DE PAUL L. REV. 215, 225 (1979).

68. *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979). The C.C.P.A. noted that while *Flook* (and *Benson*) concerned rejected process claims, the process claims in *Bergy* and *Chakrabarty* had been approved. The court also pointed out that the *Flook* holding had been limited to improved methods of calculation. *Id.* at 964.

69. See notes 71-73 and accompanying text *infra*. In a footnote the Court lamented "it is not entirely clear why a process claim is any more or less patentable because the specific end use contemplated is the only one for which the algorithm has any practical application." *Parker v. Flook*, 437 U.S. at 590 n.11. The Court also

able simply because it contains a law of nature or a mathematical algorithm." Nevertheless, "[t]he process itself, not merely the mathematical algorithm, must be new and useful."⁷⁰

The applicant in *Flook* argued that his claims differed from those in *Benson* because he intended to use the formula in a limited way⁷¹ and did not seek to preempt the use of the algorithm.⁷² The Court rejected this distinction,⁷³ citing *O'Reilly v. Morse*⁷⁴ for the rule that a mathematical algorithm or a law of nature is always treated as though it were a familiar part of the prior art.⁷⁵

The C.C.P.A. found that the Supreme Court's admonition in *Flook* calling for caution and restraint⁷⁶ pertained only to "territorial" patent rights, not subject matter, and as such did not apply to *Bergy* or *Chakrabarty*.⁷⁷ The C.C.P.A. therefore upheld the patent claims in both actions.⁷⁸

*Diamond v. Chakrabarty*⁷⁹

A divided Supreme Court affirmed the C.C.P.A.'s holding that

pointed out that "[t]he line between a patentable 'process' and an unpatentable 'principle' is not always clear." *Id.* at 589.

70. *Id.* at 590.

71. *Id.* at 589-90. In rejecting the claim for the algorithm in *Benson* the Supreme Court relied on the fact that the claim was "so abstract and sweeping as to cover both known and unknown uses . . .," *Gottschalk v. Benson*, 409 U.S. at 68, so as to wholly preempt the use of the formula. *Id.* at 71-72.

72. *Parker v. Flook*, 437 U.S. at 589-90; *Gottschalk v. Benson*, 409 U.S. at 71-72.

73. 437 U.S. at 590.

74. 56 U.S. (15 How.) 62 (1853).

75. This is true "[w]hether the algorithm was in fact known or unknown at the time of the claimed invention." 437 U.S. at 591-92 (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 115 (1853)). See notes 27-30 and accompanying text *supra*.

76. See notes 64-67 and accompanying text *supra*.

77. "The patent statute grants to the patentee the right to exclude others from making, using, or selling the subject matter of the invention throughout the United States." 8 A. DELLER, DELLER'S WALKER ON PATENTS 223 (2d ed. 1964); *In re Bergy*, 596 F.2d at 966. The C.C.P.A. stated that while the territorial jurisdiction of patent protection is fixed by statute and case law, the subject matter covered is open to interpretation by the courts. Thus it characterized *In re Bergy* as a case of first impression. See Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101: Parker v. Bergy (Parker v. Chakrabarty)*, 15 NEW ENG. L. REV. 379, 391 (1980).

78. *In re Bergy*, 596 F.2d at 987.

79. 100 S. Ct. 2204 (1980). Following the C.C.P.A.'s decision in *Bergy*, the PTO sought certiorari. This was granted as to both *Bergy* and *Chakrabarty*. *Id.* at 261 (1980). A number of commentators, apparently agreeing with Judge Miller's dissent in *Bergy*, argued that the Supreme Court should refrain from hearing the case pending congressional guidance. See, e.g., Gutttag, *supra* note 24; Note, *Patenting the Microorganism: In re Bergy, The First Step up the Chain of Life*, 2

Chakrabarty's bacterium was patentable.⁸⁰ The decision was based on two grounds. First, "in choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated the patent laws would be given wide scope;" and the courts should not read into the patent laws limitations that Congress has not expressed.⁸¹ Second, although "laws of nature, physical phenomenon, and abstract ideas have been held not patentable," Chakrabarty's claim speaks to none of these "but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity, 'having a distinctive name, character [and] use' " with "the potential for significant utility."⁸²

The Court rejected the two arguments raised by the Patent Office.⁸³ The Court held the Plant Patent Act and Plant Variety Protection Act inapplicable to microorganism patent claims.⁸⁴ It stressed the lack of ambiguity⁸⁵ in the broad terms of the patent

GEO. MASON U.L. REV. 265 (1978); Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: In re Bergy, 91 HARV. L. REV. 1357 (1978); Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: In re Bergy, 58 NEB. L. REV. 303 (1978); Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: Parker v. Bergy (Parker v. Chakrabarty), 15 NEW ENG. L. REV. 379 (1980); Note, *Patentability of Micro-Organisms: Legal Control of Life*, 47 U. MO. KAN. CITY L. REV. 130 (1978). *Bergy* was later dismissed as moot. 444 U.S. 1028 (1980). The *Bergy* patent claims were cancelled in a motion to vacate. 462 PAT. TRADEMARK & COPYRIGHT J. (BNA) A-11 (1980); 461 PAT. TRADEMARK & COPYRIGHT J. (BNA) A-8 to A-9 (1980).

80. *Diamond v. Chakrabarty*, 100 S. Ct. 2204 (1980) (5-4 decision; Brennan, J., White, J., Marshall, J., and Powell, J., dissenting). Regrettably, the Court did not have the opportunity to consider if Chakrabarty's claim was distinguishable from Bergy's claim to a biologically pure culture of an organism existing in nature, and it chose to decide the issue narrowly. The Court said: "Specifically, we must determine whether *respondent's* micro-organism constitutes a 'manufacture' or 'composition of matter' within the meaning of [§ 101]." (emphasis added). *Id.* at 2207.

81. *Id.* at 2207.

82. *Id.* at 2208.

83. *Id.*

84. *Id.* at 2209. The Court determined that the 1930 Act had been passed to overcome two obstacles to the patentability of plants. "The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law." The Act recognized the distinction for purposes of patentability should be between products of nature and human-made inventions, not between living and inanimate things. Since Chakrabarty's bacterium was clearly not a product of "nature," the Court correctly determined that it was not unpatentable on that ground. *Id.* at 2210.

The second barrier overcome by the 1930 Act was the specificity necessitated by the written description requirement of 35 U.S.C. § 112 (1976). See note 17 and accompanying text *supra*. The Court noted that Congress relaxed the specificity required of Plant Patent claims but failed to explain why Chakrabarty's microorganism was not limited by the § 112 requirements. 100 S. Ct. at 2209. See *Hearings on H.R. 11372 Before the House Committee on Patents*, 71 Cong., 2d Sess., § 4, 7 (1930) (memorandum of Patent Commissioner Robertson). See notes 110-11 and accompanying text *infra*.

85. The PTO had suggested that, due to the ambiguity of the patent statutes,

statutes⁸⁶ and decided that microorganisms are statutory subject matter. When challenged by its own language in *Flook*, that the courts must proceed cautiously when asked to extend patent rights into areas wholly unforeseen by Congress,⁸⁷ the Court restricted *Flook* to claims involving "ideas" or "phenomena of nature."⁸⁸

In an attempt to buttress its argument, the Patent Office pointed out the serious hazards inherent in genetic research. The PTO asked the Court to weigh the hazards to the public when considering patentability of microorganisms under section 101.⁸⁹

microorganisms were not patentable until Congress expressly authorized such protection. Although the Supreme Court considered the ambiguity of § 101, it failed to consider the ambiguity of the Plant Patent Acts as they relate to § 101. In its discussion of the 1970 Act, the Court said that the legislative history gave no guidance as to its applicability to microorganisms: "[I]t may simply reflect congressional agreement with the result . . . [in] *In re Arzberger* . . . [o]r it may reflect the fact that prior to 1970 the Patent Office had issued patents for bacteria under § 101." 100 S. Ct. at 2210. (In *In re Arzberger*, 112 F.2d 834 (C.C.P.A. 1940), the C.C.P.A. had determined that the congressional intent underlying the Plant Patent laws was not to include bacteria as patentable subject matter.) Despite this ambiguity the Court refused to await congressional guidance. See, e.g., Guttag, *supra* note 24, at 263, 270; Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101: Parker v. Bergy (Parker v. Chakrabarty)*, 15 NEW ENG. L. REV. 379, 401 (1980); Note, *supra* note 7, at 193.

Judge Miller in *Bergy* pointed out that, under *Parker v. Flook*, 437 U.S. 584 (1978), the courts must defer interpretation of patent law in favor of Congress if a basis for substantial doubt exists as to congressional intent regarding the statutory language. He contended the Plant Patent Act provided a substantial basis of doubt as to microorganism patents, and he called on Congress to act to define the law in this area. *In re Bergy*, 596 F.2d 952, 999 (C.C.P.A. 1979) (Miller, J., dissenting).

A second source of ambiguity is what relation, if any, may exist between the NIH Guidelines on genetic research authorized by Congress, and the lack of any congressional intent to encourage private genetic research by allowing patent grants on microorganisms. U.S. Dep't of HEW, National Institutes of Health, Recombinant DNA Research, Guidelines, 41 Fed. Reg. 27,902 (1976); U.S. Dep't of HEW, National Institutes of Health, Recombinant DNA Research, Revised Guidelines, 43 Fed. Reg. 60,080 (1978) [hereinafter cited as NIH Guidelines].

86. The Court pointed out that broad language is not necessarily ambiguous, and the patent statute cannot be restricted to specific applications foreseen by the legislators as the broad language was adopted principally because patentable inventions are frequently unforeseeable. *Diamond v. Chakrabarty*, 100 S. Ct. at 2211.

87. See note 65 *supra*.

88. 100 S. Ct. at 2211.

89. *Id.* See notes 154-60 and accompanying text *infra*. The Court could have avoided this issue, at least in Chakrabarty's case, by acknowledging that the *Pseudomonas aeruginosa* bacterium used by Chakrabarty had been expressly excluded from the NIH Guidelines as non-hazardous. See NIH Guidelines, *supra* note 85, at 60,130.

The Supreme Court recognized the potential hazards but refused to consider them. The Court argued that denying patents for microorganisms is not likely to end genetic research and its risks because a great deal of research has already occurred without assurances of patentability.⁹⁰ At best, said the Court, the research efforts will only be slowed or accelerated by the incentives of patentability.⁹¹ Thus limited, the Court had no alternative but to authorize Chakrabarty's patent.

In light of the risks inherent in genetic research and the Court's admitted institutional incompetence to determine the desirability of encouraging such research, the Court's decision to extend patent protection to products of genetic research was not compelled by statute or case law.⁹² The Court had several methods available to exclude the products of genetic engineering from patentability.

Statutory Ambiguity

The courts have two optional approaches to the determination of patentability. The first is to interpret the patent statutes freely, in view of their broad general language, unless there is an explicit limitation on patentability.⁹³ The second is to determine whether the subject matter sought to be patented is clearly within the statutory intent. If it is not, the statute should be construed narrowly so as to exclude the claim.⁹⁴

When the Supreme Court summarily remanded *Bergy* for reconsideration in light of *Flook*, many thought the Court was adopting this cautious second approach.⁹⁵ The C.C.P.A.'s decision in *In re Arzberger*⁹⁶ would have supported the non-patentability

90. 100 S. Ct. at 2211-12.

91. *Id.* at 2212.

92. *Id.* at 2211-12. This Comment will treat the Court's decision as promulgating a broad rule of patentability of genetically engineered microorganisms despite the Court's having ostensibly limited the holding to the facts of the case.

93. *See, e.g.*, Note, *supra* note 7, at 199. The author suggests that the courts' only duty in determining patentability is to decide whether the patent law excludes the subject matter. If ambiguities in the statutes confuse this determination, the courts should extend the patent and let Congress correct any errors or ambiguities.

94. Arguably, this is the position that was taken by the Supreme Court in *Flook* when it said that the courts "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress." *Parker v. Flook*, 437 U.S. 584, 596 (1978). "This policy rests on the principle that the courts should not expand patent protection by overruling or modifying prior cases construing the Patent Act without a clear and certain signal from Congress." Note, *supra* note 7, at 185. *See* Note, *Patenting the Microorganism: In re Bergy, The First Step up the Chain of Life*, 2 GEO. MASON U. L. REV. 265, 278 (1978).

95. *See* notes 65-67 and accompanying text *supra*.

96. 112 F.2d 834 (C.C.P.A. 1940). *See* note 85 *supra*.

of microorganisms.⁹⁷ The PTO's patent grants to inventions involving microorganisms would not prevent the Court from so holding.⁹⁸ Nevertheless, the Court adopted the first approach in *Diamond v. Chakrabarty*, and refused to consider the "policy" issues despite the long history of judicial policy decisions on patentability in the form of judicially created limitations on patentability.⁹⁹

The Court should have determined whether the subject matter sought to be patented, genetically engineered microorganisms, was clearly within the legislative intent of the patent statutes. Although the majority of the Court said the statutes were clear,¹⁰⁰ four of the nine justices disagreed.¹⁰¹ Many commentators and members of the judiciary have argued that the statutes are ambiguous and the legislative intent unclear about the patentability of microorganisms.¹⁰² These critics have called for congressional clarification.¹⁰³

Other Grounds for Rejecting the Microorganism Claim

Even accepting the Court's conclusion that neither the patent statute nor the legislative intent is ambiguous,¹⁰⁴ the Court was not without other means to reject the microorganism claims as unpatentable. Although the product of nature doctrine was not available, because Chakrabarty's organism was man-made,¹⁰⁵ the phenomenon of nature doctrine can be applied to the claim. Judge Baldwin, concurring in *Bergy*,¹⁰⁶ described the phenomenon in *Chakrabarty* as any biological metabolism of hydrocar-

97. *Id.*

98. See *Diamond v. Chakrabarty*, 100 S. Ct. at 2210 n.9; Daus, Bond & Rose, *Microbiological Plant Patents*, 10 IDEA 87, 94 n.36 (1966) (citing several examples of patents issued for claims involving living microorganisms. Some of the claims are distinguishable as processes or inocula; none involve genetic engineering nor were any challenged in the courts on the issue presented in *Chakrabarty*). See notes 35 and 42 and accompanying text *supra*.

99. See notes 23-34 and accompanying text, *supra*, showing that courts have denied patents to claims even in the absence of statutory authority or legislative intent so indicating.

100. *Diamond v. Chakrabarty*, 100 S. Ct. 2204, 2211 (1980).

101. *Id.* at 2213 (Brennan, J., White, J., Marshall, J., and Powell, J., dissenting).

102. See note 44 *supra*.

103. See note 79 *supra*.

104. *Diamond v. Chakrabarty*, 100 S. Ct. at 2212.

105. *Id.* at 2208.

106. See note 85 and accompanying text *supra*. *In re Bergy*, 596 F.2d 952, 997 (C.C.P.A. 1979) (Baldwin, J., concurring).

bons.¹⁰⁷ Had the phenomenon been phrased as the ability of strains of the genus *Pseudomonas* to metabolize hydrocarbons, the doctrine could have been invoked, because the patent claim included naturally occurring strains of that genus.¹⁰⁸

The Court might have seized the Plant Patent Act argument adopted by the *Chakrabarty* minority¹⁰⁹ to exclude microorganisms from patentability.

The Court might also have rejected the application on the ground that it failed to meet the description requirements of section 112.¹¹⁰ Although Bergy's *Streptomyces vellosus* could have met the current requirement of a taxonomic description accompanying the deposit of a culture sample, it is doubtful that a more complex, recombinant organism like Chakrabarty's *Pseudomonas* could do so.¹¹¹ The Court could also have characterized the grant-

107. 100 S. Ct. at 2208. There is evidence Bergy's claim was withdrawn in anticipation that the Supreme Court might seize the phenomenon of nature doctrine to exclude it from patentability. Cooper, *Arzberger Under the Microscope: A Critical Reexamination of the Exclusion of Bacteria from Plant Patent Protection*, 7 RUTGERS J. COMP., TECH. & LAW 367, 379 n.9 (1980) (editor's postscript).

108. Judge Baldwin noted that Chakrabarty's claim would not preempt the biological metabolism of hydrocarbons. Nevertheless, Chakrabarty's Claims 21 and 30 claimed an inoculum and an inoculated medium containing bacterium of the genus *Pseudomonas* "at least some of which" are the genetically engineered organisms produced by Chakrabarty. *In re Bergy*, 596 F.2d at 996-97. Because a number of naturally occurring strains of the genus *Pseudomonas* can also degrade hydrocarbons and are claimed in the patent application, the patent claims a phenomenon of nature at least as to those organisms. See Note, *supra* note 7, at 195.

109. 100 S. Ct. at 2213.

110. See notes 17, 84, and accompanying text *supra*.

111. Although the PTO has no legislative mandate to require that a patent application for a microorganism be accompanied by a representative culture, the present regulations issued by the Patent Commission require that the subject microorganism be deposited in the Northern Regional Research Laboratories, along with a taxonomic description of the organism. Behr, *The Prescient Microbe or Where to Deposit a Foreign Body*, 57 J. PAT. OFF. SOC'Y 28 (1975). See *In re Argoudelis*, 434 F.2d 1390 (C.C.P.A. 1970). It is doubtful that complex genetically recombinant organisms, or multi-cellular cultures, can meet the taxonomic description requirement. In determining the patentability of a microorganism, the Patent Examiner must deal solely with the written description. Even with the deposit it is extremely difficult to tell if strains of the same species are the same or different. Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: Parker v. Bergy (Parker v. Chakrabarty), 15 NEW ENG. L. REV. 379, 403 (1980); Robbins, *Patents for Microbiological Transformations—An International Problem*, 42 J. PAT. OFF. SOC'Y 830, 833-34, 838 (1960).

It has been argued that the present deposit and taxonomic description standard does not adequately describe the patented subject matter so as to give the public the information the patent system is supposed to provide, Gutttag, *supra* note 24, at 277, or to give adequate warning to infringers that they are violating the law. Note, *Patentability of Micro-Organisms: Legal Control of Life*, 47 U. MO. KAN. CTRY L. REV. 130, 142 (1978). The present "deposit" system may also lead to problems of storage. The microorganisms now on deposit are commonly occurring and easy to maintain. Nevertheless, as research advances and more complex recombinant or symbiotic multi-organism cultures become increasingly common,

ing of patents for microorganisms as an expansion of patent rights into an area unforeseen by Congress. The Court could have refused to uphold the patent based on the language in *Flook*¹¹² rather than limiting the holding to algorithms and phenomena of nature.¹¹³

Preemption of Improvements

As previously noted, the *Flook* decision relied on *O'Reilly v. Morse* to deny a patent claim for a mathematical algorithm.¹¹⁴ The underlying rationale in *Morse* was not that the claim contained a "scientific principle," as the *Bergy* and *Flook* Courts professed, but that the claimed application of the principle was too broad. The *Morse* Court denied the patent claim because to have allowed it would have prohibited or impeded development in a useful art.

When Morse submitted his patent application for the telegraph, many scientists throughout the world were conducting experiments in the new and relatively unexplored field of electromagnetism.¹¹⁵ In his patent claim, Morse sought the exclusive right to every invention in which the motive power was electric current and the result was the marking of intelligible characters at a distance.¹¹⁶ The Supreme Court pointed out that if such a claim were allowed, a future inventor would be precluded from obtaining a patent even though his invention might be less complicated, less expensive in operation and construction, and more reliable. The *Morse* Court apparently feared that too broad a claim would discourage later research and improvements benefi-

the maintenance of these fastidious cultures may become more difficult and expensive. Note, *Ownership of Living Inventions*—In re Bergy, 29 DE PAUL L. REV. 215, 234-35 (1979). (The author also notes that higher forms of life may be unpatentable because of their inability to meet the requirement that the description be sufficient to allow one skilled in the art to make and use the invention. *Id.* at 235.) See also *In re Bergy*, 596 F.2d at 997 n.7 (Baldwin, J., concurring) (noting the "inherent difficulty in complying with the enablement provisions of 35 U.S.C. § 112" as to more complex life forms).

112. See note 65 *supra*.

113. 100 S. Ct. at 2211.

114. See notes 73-75 and accompanying text *supra*.

115. *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 106 (1853).

116. In Claim 8 Morse stated: "I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current" *Id.* at 112.

cial to the public.¹¹⁷ Thus, based on constitutional and legislative intent, the Court held that a patent confers on the inventor "the exclusive right to use the means specified to produce the result he describes, and nothing more."¹¹⁸

The Court has granted patents, despite the inclusion of a scientific principle or mathematical algorithm when the claimed uses of a principle in a process are sufficiently limited.¹¹⁹ The *Flook* Court cited *Mackay Radio & Telegraph Co. v. Radio Corp. of America*¹²⁰ for the proposition that *Morse* requires the process incorporating the algorithm be "new and useful."¹²¹ *Mackay*, however, was not decided on the basis of novelty or usefulness of the invention.¹²² The *Mackay* Court based its decision on the fact that the application of the principle in the patent claim was a narrow one, and the claim was strictly construed.¹²³ The fact the claimed invention may be new and useful has no bearing on whether it is stated too broadly.

The C.C.P.A., in dismissing *Flook* as inapplicable to *Bergy* and *Chakrabarty*, considered only one aspect of the rationale for the rejection of the patent claims in *Flook*. The court recognized that the *Flook* claims involved an unpatentable "principle," but failed to consider the claims might be so overbroad and unspecific as to preempt future improvements.¹²⁴

117. The Court was concerned that *Morse*, the earlier patent grantee, would be able to incorporate all of the new discoveries and developments without having to record a description with the patent office, thus depriving the public of the details. *Id.* at 113.

118. *Id.* at 119.

119. See *Mackay Radio & Tel. Co. v. Radio Corp. of America*, 306 U.S. 86 (1939); *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923); *Tilghman v. Proctor*, 102 U.S. 707 (1880).

120. 306 U.S. 86 (1939).

121. *Parker v. Flook*, 437 U.S. 584, 591 (1978) (citing *Mackay Radio & Tel. Co. v. Radio Corp. of America*, 306 U.S. at 94). See also Note, *Life Forms as Proper Subject Matter Under the Patent Act: Diamond v. Chakrabarty*, 1980 DET. COLL. L. REV. 939, 951-53 (1980).

122. The *Mackay* Court stated: "We assume, without deciding the point, that this advance was invention even though it was achieved by the logical application of a known scientific law to a familiar type of antenna." 306 U.S. at 94.

123. The Court refused to accept the ruling of the court of appeals that *Mackay*'s patent applied to antennas, using all lengths of wire and all angles, that embraced the patent's empirical formula. Where the later inventor specified exact angles and lengths for wire, the prior patent grantee could not establish infringement. *Id.*

124. See notes 127-34 and accompanying text *infra* for a discussion of possible preemption of improvements or discoveries in the field due to the *Chakrabarty* patent grant. Judge Baldwin in his concurring opinion alludes to this preemption problem but restricts the discussion to "natural phenomenon" and "scientific principles," joining the court on the ground that a bacterium is not a "principle" and that *Bergy* and *Chakrabarty* did not seek to wholly preempt the use of the "phenomenon." *In re Bergy*, 596 F.2d 952, 988, 990, 997 (C.C.P.A. 1979) (Baldwin, J., con-

A patent on a process or manufacture employing a scientific principle or mathematical algorithm may be denied for two reasons. Under the "phenomenon of nature" doctrine, the principle or algorithm is not considered a discovery or invention, even when the formula has no other practical application.¹²⁵ Alternatively, the court may find that the claim is overbroad and upholding the patent on the principle or algorithm would inhibit improvements in design, manufacture, or operation through other applications of the principle.

The *Chakrabarty* Court failed to fully consider the doctrine of preemption. Judge Baldwin in *Bergy* recognized that other strains of bacteria are capable of degrading hydrocarbons and he concluded that Chakrabarty's patent would not altogether preempt biological metabolism of hydrocarbons.¹²⁶ He failed to note, however, that the patented organism might have other uses.

Given the infant state of the genetic engineering field and the lack of information on the functioning of the genetic coding process, it is unlikely that a researcher who develops a new strain of an organism will have sufficient prescience to anticipate all possible uses of his organism. An organism capable of producing one therapeutic drug might serendipitously be discovered to produce yet another drug in a different process.¹²⁷ It is rare for the originally developed organism to be the most useful commercially. Later researchers often make substantial improvements.¹²⁸ The original use may be trivial when compared to later derivations and improvements.¹²⁹ Should the Court inhibit such later discoveries by granting a patent covering every process and use employing the microorganism? This would require researchers to obtain licenses in order to use the new organism.¹³⁰ Such a policy would

curing). See Note, *Ownership of Living Inventions*—In re Bergy, 29 DE PAUL L. REV. 215, 226 (1979). One commentator has seized on Judge Baldwin's concurrence to criticize the decision in *Bergy*. See Note, *supra* note 7, at 193-94.

125. See, e.g., *In re Chatfield*, 545 F.2d 152, 161 (C.C.P.A. 1976); notes 29-30 and accompanying text *supra*. This was the position taken in *Flook*. See notes 69-75 and accompanying text *supra*.

126. See note 108 and accompanying text *supra*.

127. Kitch, *supra* note 6 at 269; Note, *Patenting the Microorganism: In re Bergy, The First Step up the Chain of Life*, 2 GEO. MASON U.L. REV. 265, 268 (1978).

128. Robbins, *Patents for Microbiological Transformations—An International Problem*, 42 J. PAT. OFF. SOC'Y 830 (1960).

129. *Id.* at 840.

130. The patent grants the right to exclude others from making, using, or selling the patented subject matter. The patentee may give or deny licenses to use the

discourage research by others and slow or deter improvements in the manufacture and application of the organism.¹³¹ This is directly contrary to the mandate of the Constitution¹³² and to the holdings in *Morse*¹³³ and *Mackay*.¹³⁴

An inventor of a novel organism can be adequately protected without receiving a patent on the microorganism itself.¹³⁵ The PTO has traditionally allowed patents on processes or inocula utilizing microorganisms.¹³⁶ Allowing a patent on a process or specific use of the organism would protect the inventor's discovery while allowing the microorganism to be used by the public.¹³⁷ This policy would enhance the probability of later improvements in the patented process employing the organism, or in other distinct processes using it, by encouraging research by scientists who presumably could patent their discoveries if they met the novelty and nonobviousness requirements of sections 102 and 103.

In Chakrabarty's case, the patent could have been limited to use of the microorganism to clean up oil spills. If further uses are discovered later, they too might be patentable. Currently, General Electric, as assignee of Chakrabarty's patent,¹³⁸ could decide

subject matter for reasons wholly within his discretion, and he need not license anyone at all. 8 A. DELLER, *DELLER'S WALKER ON PATENTS* 214, 225 (2d ed. 1964). A solution to this may be compulsory licensing of microorganism patents. See Kitch, *supra* note 6, at 286-87.

131. But see Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101: Parker v. Bergy* (Parker v. Chakrabarty), 15 NEW ENG. L. REV. 379, 404 (1980) (author generally supports patentability of microorganisms).

132. See note 1 and accompanying text *supra*.

133. See notes 117-18 and accompanying text *supra*.

134. See note 123 and accompanying text *supra*.

135. Cf. Note, *Patentability of Micro-Organisms: Legal Control of Life*, 47 U. MO. KAN. CITY L. REV. 130, 139-40 (1978) (author suggests even patents on the microorganisms themselves would provide inadequate protection).

136. Note, *Patenting the Microorganism: In re Bergy, The First Step up the Chain of Life*, 2 GEO. MASON U.L. REV. 265, 270 (1978). See, e.g., *Guaranty Trust Co. of New York v. Union Solvents Corp.*, 54 F.2d 400 (D. Del. 1931), *aff'd per curiam*, 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933) (microorganism used in process accelerating fermentation of butyl alcohol and acetone); *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453 (2d Cir.), *cert. denied*, 209 U.S. 548 (1908) (bacteria used in a sewage treatment process).

137. But see Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101: In re Bergy*, 58 NEB. L. REV. 303, 328-29 (1978), which suggests that such a policy avoids the virtually impossible task of trying to duplicate the microorganism by requiring the microorganism to be placed on deposits the public may gain access to it, while the microorganism itself should be patentable so the developer will benefit from every use of the strain, even those that he did not contemplate. There are two problems with this view. First, it assumes the purpose of the patent system is to reward inventors rather than to promote the useful arts. See note 7 and accompanying text *supra*. Second, it fails to explain how the grant of a monopoly on a strain of bacterium will encourage others to conduct research for other possible uses of that strain.

138. See note 48 *supra*.

not to license other researchers and could forestall improvements or further uses of the bacteria. The Court should have rejected the *Chakrabarty* claim as overbroad or lacking in specificity.

The Supreme Court and Public Policy

Most importantly, the Supreme Court is not entirely incapable of acting on the policy considerations underlying the patentability of microorganisms developed by genetic engineering.¹³⁹ In granting the patent on a product of genetic research the Court must have determined the hazards of such research were not substantial enough to warrant immediate protective action.¹⁴⁰ This in itself was an "act" based on the constitutional policy of encouraging research in the useful arts as expressed through legislative intent.¹⁴¹

The Court might as easily have based its decision on the constitutional policy of excluding from patentability subject matter that threatens injury to the well-being, good policy or morals of the society,¹⁴² and then refused to act without congressional guidance. Determinations of patentability have often been highly subjective, inconsistent with statutory intent,¹⁴³ arbitrary, unexplained,¹⁴⁴ based on judicially created limitations¹⁴⁵ or on judicial fiat.¹⁴⁶ Thus it is not unreasonable for the Court to refuse patent incentives for research that may be injurious to the public weal.

The Supreme Court has made a decision encouraging private party participation in recombinant DNA research.¹⁴⁷ It is true that if Congress decides the statutes are being improperly applied it may change or clarify them.¹⁴⁸ Until that time it is preferable that the courts adopt a narrow interpretation of the patent statutes in this area. In view of the uncertain legislative intent and the potential hazards of genetic research it seems imprudent to

139. *But see* *Diamond v. Chakrabarty*, 100 S. Ct. 2204, 2212 (1980), where the Court indicated it was unable to consider the policy arguments, either to brush aside the hazards of genetic research as groundless fears or to act on them.

140. *Id.*

141. *Id.* at 2206-07.

142. *See* note 8 and accompanying text *supra*.

143. Gutttag, *supra* note 24, at 276-77.

144. *See* notes 31-34 *supra*.

145. *See* text accompanying notes 18-30 *supra*.

146. *See* note 37 and accompanying text *supra*.

147. *See* *TIME*, March 9, 1981, at 52.

148. 100 S. Ct. 2204, 2211 (1980).

give patent incentives to such research by broadly construing the patent statutes.¹⁴⁹ Regardless of the ultimate desirability of extending patent protection to products of genetic research, it would be wiser to provide Congress and the public with the opportunity to debate the issue and to create a system that regulates private research in recombinant genetics.

THE PROPRIETY OF PATENTING PRODUCTS OF GENETIC RESEARCH

Man's ability to alter his environment has developed far more rapidly than his ability to foresee with certainty the effects of his alterations. It is only recently that we have begun to appreciate the danger posed by unregulated modification of the world around us, and have created watchdog agencies whose task it is to warn us, and protect us, when technological "advances" present dangers unappreciated—or unrevealed—by their supporters. Such agencies unequipped with crystal balls and unable to read the future, are nonetheless charged with evaluating the effects of unprecedented environmental modifications, often made on a massive scale. Necessarily, they must deal with predictions and uncertainty, with developing evidence, with conflicting evidence, and, sometimes, with little or no evidence at all.¹⁵⁰

Environmental Risks

Critics of genetic research warn, that by creating new organisms, scientists are opening a pandora's box of evils which they are ill equipped to control. The doomsayers counsel it is often better "to bear those ills we have than to fly to others that we know not of."¹⁵¹ Recent developments in other technical fields may prove them right. Scientists themselves have recognized that many new products or technologies often have unexpected environmental effects.¹⁵² Pesticides and chemical waste have proven to be toxic to wildlife and man, gases used in spray cans deplete the earth's ozone layer, and many common substances are now known to cause cancer.¹⁵³

Nightmarish scenarios involving manmade organisms have been suggested. For example, an insulin producing bacterium might find its way into the human body, producing insulin

149. *Id.* at 2207, 2211.

150. *Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1, 26 (D.C. Cir. 1976) (cited in G. Halbert, *Developing a Governmental Policy for the Regulation of Environmental Mutagens and Teratogens: Shopping at the Grand Bazaar*, in *GENETICS AND THE LAW II*, 426-27 (A. Milunsky ed. 1980)).

151. 100 S. Ct. at 2211.

152. B. Davis, *Three Specters: Dangerous Products, Powers or Ideas*, in *GENETICS AND THE LAW II* 3 (A. Milunsky ed. 1980).

153. *Recombinant DNA Research Act of 1977: Hearings on H.R. 4759, 4889, 3191, 3591, 3592, 5020, 4232 and H. Res.131 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. 303 (1977) (statement of Pamela Lippe).

shock.¹⁵⁴ An oil-eating bacterium might escape from oil spills to devour oil in machinery.¹⁵⁵ While these flights of fancy may merely be amusing conjecture, more substantial threats have occurred. Dr. Chakrabarty himself transferred a gene that produces cellulase¹⁵⁶ into *E. coli* bacteria.¹⁵⁷ Dr. Chakrabarty destroyed the bug when warned that, should it be transmitted into the general population, countless people might be inflicted with chronic or fatal diarrhea.¹⁵⁸ In 1971 Dr. Berg of Stanford University implanted a cancer causing virus into *E. coli* bacteria. He too destroyed the bacteria when other scientists alerted him to the danger to society should it escape.¹⁵⁹ In 1980 Dr. Ian Kennedy of the University of California, San Diego, apparently unwittingly conducted experiments with a strain of *Simliki* forest virus, which had been banned from use in research by National Institutes of Health Guidelines, thinking it was a harmless strain of *sindibus* virus. Purely by good fortune the experiments were conducted in a secure laboratory and the organisms were later safely destroyed.¹⁶⁰ The potential harm to the public in these cases was luckily averted, statistically, as research in this area increases, we may not continue to be so fortunate.

Recombinant DNA research has significant potential value to society and its substantial benefits should be noted. Apart from generally advancing human understanding of biological functions, microbiological research has developed organisms that can produce the fuel additive ethanol, penicillin, somastatin (used in treatment of hormonal disorders), thymosin alpha-1 (used to treat certain brain and lung cancers), insulin (used to control diabetes), and interferon (a potential cancer cure).¹⁶¹ Genetic research

154. U.S. Dep't of HEW, National Institutes of Health, Decision of the Director, National Institutes of Health to Release Guidelines for Research on Recombinant DNA Molecules, 41 Fed. Reg. 27,902, 27,908 (1976).

155. Wald, *The Case Against Genetic Engineering*, THE SCIENCES, Sept./Oct. 1976, at 10.

156. An enzyme which breaks down the structural plant protein cellulose. Cellulose is indigestible by man and therefore gives bulk to feces.

157. *Escherichia coli* is the most common host organism used in recombinant DNA research. It inhabits the soil, water, and the intestines of all warm-blooded animals, including man.

158. Note, *Ownership of Living Inventions*—In re Bergy, 29 DEPAUL L. REV. 215, 233, n.119 (1979).

159. Bennett & Gurin, *Science that Frightens Scientists*, THE ATLANTIC MONTHLY, Feb. 1977, at 43.

160. Los Angeles Times, Aug. 7, 1980, at 1, col. 1.

161. TIME, Oct. 20, 1980, at 72.

has great promise of increasing the over-all health and well-being of society. Some scientists have suggested that the fears of the critics might be overblown.¹⁶² Thus it appears genetic engineering may be a Janus of sorts, presenting both spectacular potential for benefits to the public and foreboding possibilities of irreparable harm to public health and safety.

Philosophical Considerations

Recombinant DNA research also poses unique philosophical and moral questions. "The power to design life according to man's intellect is repugnant to many people; it assumes omniscience too close to God for many to accept. Recombinant research may present man with another forbidden fruit decision—whether to place the course of all evolution into our own hands."¹⁶³

It is the province of Congress to decide these essentially moral issues, to balance the needs of society with threats to public health, morals and well-being.¹⁶⁴ Yet the Supreme Court, by allowing patentability of products of genetic research, has made these decisions while reciting its institutional incompetence to do so.¹⁶⁵ The Court has noted "the grant or denial of patents on microorganisms is not likely to put an end to genetic research or to its attendant risks" since substantial research has already occurred in the absence of patent protection for researchers.¹⁶⁶ The Court dismissed as inconsequential the fact that the determination of patentability may either accelerate or slow genetic research through manipulation of the patent incentives which encourage private participation in genetic research.¹⁶⁷ It is precisely this uncontrolled, privately funded genetic research which calls for caution.

Unregulated Genetic Research

Until recently, much of the research in this field has been federally funded. The Supreme Court's *Diamond v. Chakrabarty* decision preceded an increase in awareness by private industry of the potential of genetic research. Several small genetic engineering

162. Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: Parker v. Bergy (Parker v. Chakrabarty), 15 NEW ENG. L. REV. 379, 403 (1980).

163. Berger, *Government Regulation of the Pursuit of Knowledge: The Recombinant DNA Controversy*, 3 VT. L. REV. 83, 89 (1978).

164. *Id.* at 98-99.

165. *Diamond v. Chakrabarty*, 100 S. Ct. 2204, 2212 (1980).

166. *Id.* at 2211-12.

167. *Id.* at 2212.

firms have appeared over the past four years,¹⁶⁸ and now giant multi-national corporations with capital sufficient to fund major research projects are about to enter the field.¹⁶⁹ While it may be true that recombinant DNA technology is not likely to achieve its full promise absent private financial and intellectual support,¹⁷⁰ it is not clear that private industry participation in such a potentially dangerous field should be encouraged until adequate guidelines are formulated to regulate private genetic research. Congress has not enacted legislation to govern either private or publicly funded recombinant DNA research.¹⁷¹

The Supreme Court's decision to afford patent protection to products of recombinant DNA research will provide a major incentive to the private development of new microorganisms.¹⁷² Private enterprises are motivated by profit. If competition exists, profit provides incentive for efficient resource allocation through increased output. But sole control of any scarce and unique resource makes for less output and higher prices for that resource. Patents create sole control of the patented resource. Where monopolistic control exists, the profit motive leads to trade restriction. A central goal of patent law is the resolution of this efficiency/trade restriction dilemma.¹⁷³ It has been contended patent protection is not essential for continuing the research of large corporations.¹⁷⁴ While this may be true, the patentability of products of genetic research clearly will not discourage private corporate involvement in the field and does act to enhance profitability of such research.

The interface of the patentability of microorganisms, the encouragement of private genetic engineering, and the lack of effective guidelines to regulate recombinant DNA research is

168. Wall St. J., Oct. 16, 1980, at 47, col. 3.

169. TIME, Oct. 20, 1980, at 72. Previously at least one of the small firms was sharing laboratory space and employees with federally funded research institutions governed by NIH Guidelines. Now these firms will be able to fund independent research.

170. Cripps, *Genetic Engineering—A Problem for the Patent Office?*, 1979 NEW ZEALAND L.J. 232.

171. Note, *The Patentability Of Living Organisms Under 35 U.S.C. § 101*: Parker v. Bergy (Parker v. Chakrabarty), 15 NEW ENG. L. REV. 379, 405 n.193 (1980).

172. Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: In re Bergy, 91 HARV. L. REV. 1357, 1365 (1978).

173. W. BOWMAN, PATENT AND ANTITRUST LAW 4 (1973).

174. See F. VAUGHAN, THE UNITED STATES PATENT SYSTEM 12 (1956).

complicated. Patents are awarded to the "first inventor,"¹⁷⁵ a technical status nearly always accorded the first person to file the patent application.¹⁷⁶ When technology brings an invention into the realm of possibility, the creative efforts of many scientists will likely be similarly directed.¹⁷⁷ Because the researchers are aware of each other, and because the invention need not be commercially valuable in its initial version to be patentable, the patent system results in greater secrecy in the initial stages of development and in many hastily prepared applications which are rushed to the Patent Office to establish priority.¹⁷⁸ It is not unreasonable to suppose that proper laboratory techniques and safety guidelines, voluntarily self-imposed, might be lost amid the frenetic confusion of the great race to file.

The National Institutes of Health (NIH) has promulgated genetic research guidelines under its informal rule-making authority.¹⁷⁹ The NIH Guidelines, however, apply only to research conducted at, or sponsored by an institution receiving NIH support for that research.¹⁸⁰ Even the safety of research conducted at NIH-sponsored institutions has been subjected to criticism.¹⁸¹ The NIH Guidelines depend for their effectiveness on the use of proper laboratory techniques, which may be lacking even in university research,¹⁸² and the only mechanism for enforcement consists of denial of grants by the NIH.¹⁸³ The NIH's role as both benefactor and policeman makes enforcement of the Guidelines more difficult still.¹⁸⁴

Private industry has suggested it would voluntarily follow the NIH Guidelines.¹⁸⁵ It is not required to do so, however, and there

175. See note 15 *supra*.

176. Kitch, *supra* note 6, at 269.

177. *Id.*

178. Roberts, *First to Invent—A Fading Concept?*, 61 J. PAT. OFF. SOC'Y 350, 351 (1979).

179. Hutt, *Research on Recombinant DNA Molecules: The Regulatory Issues*, 51 S. CAL. L. REV. 1435-1445 (1978).

180. NIH Guidelines, *supra* note 85, at 60,123.

181. Berger, *supra* note 163.

182. *Id.* at 91 n.26. The incident involving Dr. Kennedy, for example, occurred at a NIH sponsored laboratory. See note 160 *supra*.

183. Hutt, *supra* note 179, at 1444.

184. The Atomic Energy Commission formerly had such a dual role, but Congress considered it improper and divided the duties between the Nuclear Regulatory Commission and the Energy Research and Development Administration. Berger, *supra* note 163, at 92.

185. Hutt, *supra* note 179, at 1441-42. In order to induce private industry compliance with NIH Guidelines, the Assistant Secretary of Commerce for Science and Technology requested that the PTO give special status to patent applications involving recombinant DNA when the applicant voluntarily followed the Guidelines. That status has been revoked pending further consideration. See Patent and Trademark Off., Recombinant DNA, Accelerated Processing of Patent Applications

are no indications that it would. In light of the lack of effective guidelines and the effect the *Chakrabarty* decision will have in encouraging private genetic research, Congress must act quickly to provide adequate protection to the public.

Congress Faced with a Dilemma

It is now up to Congress to weigh the merits of genetic research against the moral questions, health risks, environmental dangers, and systematic difficulties in affording patent incentives to private genetic research.¹⁸⁶ While it may be true that encouraging genetic research is in the public interest, in reaching that decision, Congress is capable of making the in-depth investigation for which the courts are ill-equipped.¹⁸⁷ Congress is faced with serious issues. Morally and ethically, ought society seek and use the means to control the genetic structures of living organisms, and potentially those of man? In view of the danger currently posed by unregulated, private genetic research, does the federal government wish to encourage such research by giving patent incentives; and if so, what can be done to mitigate the danger?

In balancing the potential benefits of recombinant DNA research with the potential hazards, the scientists have stressed the benefits. They denigrate the critics' warnings as being "a gruesome parade of horrors" with no basis in reality.¹⁸⁸ Supporters of genetic research refute the philosophical issues by arguing that it would be unethical to forego the benefits.¹⁸⁹ The scientists' position is based partly on reason, familiarity with the facts, and logical extrapolation, and partly on their faith in themselves to control their activities.¹⁹⁰ What they fail to realize is that the determination to regulate genetic research may have less to do with

for Inventions, 42 Fed. Reg. 2,712 (1977), *suspended in part*, Patent and Trademark Off., Recombinant DNA, Suspension of Accelerated Processing of Patent Applications for Recombinant DNA Research Inventions, 42 Fed. Reg. 13,147 (1977).

186. Note, *The Patentability Of Living Organisms Under 35 U.S.C. § 101*: In re Bergy, 91 HARV. L. REV. 1357, 1365 (1978); Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*: Parker v. Bergy (Parker v. Chakrabarty), 15 NEW ENG. L. REV. 379, 405 (1980).

187. *Diamond v. Chakrabarty*, 100 S. Ct. 2204, 2212 (1980).

188. *Id.* at 2211. *Patent Decision Fuels Genetic Research Debate*, 66 A.B.A. J. 943, 944 (1980).

189. *Patent Decision Fuels Genetic Research Debate*, 66 A.B.A. J. 943, 944 (1980).

190. Fletcher, *Ethics and Recombinant DNA Research*, 51 S. CAL. L. REV. 1131, 1134 (1978).

whether the dangers are actual or imagined than it has to do with how genetic research is perceived by the populace.

The public does not share the scientists' faith in themselves. Critics contend that holders of patents on genetic research would be able to play God; that patents for genetic engineering techniques create the potential for industrial control of the earth's gene pool; and that "ownership of life" may result in the upheaval of legal, social, and moral systems.¹⁹¹

The public has a legitimate democratic right to be informed of the nature of DNA research and its hazards in order to weigh the costs and benefits. The public should make the moral choice whether genetic research should be encouraged by government patent protection.¹⁹² In the long term, with increased familiarity, the public will come to appreciate the nature of genetic research and will be better able to deal with these issues rationally.¹⁹³ Paradoxically, it appears that the freedom of the scientists to conduct research in areas such as genetic engineering, which may pose special dangers to society, is not likely to have the support of the public unless appropriate safeguards can be developed which temporarily limit that freedom.¹⁹⁴

Patents for products of genetic research, upheld by the courts in the absence of a legislative mandate, may foreclose all chance for meaningful public education and participation in the policy decisions surrounding genetic engineering. Simultaneously, the drive for commercial application of such products will escalate with apparent government support.¹⁹⁵ Public debates, demonstrations, and referenda concerning such matters as the dumping of chemical wastes and building of nuclear power plants indicate that the public desires democratic control over the technological decisions that may affect their lives.¹⁹⁶

The moral and philosophical questions, as well as the hazards and benefits, of genetic research are vital issues which should be discussed in a legislative or public forum.¹⁹⁷ It is for the people,

191. *Patent Decision Fuels Genetic Research Debate*, 66 A.B.A. J. 943, 944 (1980).

192. See generally Lappé & Martin, *The Place of the Public in the Conduct of Science*, 51 S. CAL. L. REV. 1535, 1539 (1978).

193. Neville, *Philosophic Perspectives on Freedom of Inquiry*, 51 S. CAL. L. REV. 1115, 1129 (1978). Dr. Chakrabarty has recognized that the resolution of this debate necessitates "informed people." *Patent Decision Fuels Genetic Research Debate*, 66 A.B.A. J. 943, 944 (1980).

194. Neville, *supra* note 193, at 1129. See also D. Callahan, *Ethical Issues in the Control of Science*, in *GENETICS AND THE LAW II* 19-24 (A. Milunsky ed. 1980).

195. *Patent Decision Fuels Genetic Research Debate*, 66 A.B.A. J. 943, 944 (1980) (citing an *amicus* brief in *Diamond v. Chakrabarty*).

196. Berger, *supra* note 163, at 93-94.

197. *Diamond v. Chakrabarty*, 100 S. Ct. 2204, 2211-12 (1980).

through their elected representatives, or by referendum, to decide if genetic research by private industry should be encouraged by patent incentives, if such research should first be subject to regulation, or if patents should be denied.¹⁹⁸

CONSIDERATIONS FOR CONGRESSIONAL ACTION

While Congress has not yet passed legislation governing recombinant DNA research, hearings have been held¹⁹⁹ and numerous bills have been introduced²⁰⁰ in both houses of Congress.²⁰¹ After *Diamond v. Chakrabarty*,²⁰² private industry's participation in the genetic engineering field will be stimulated and inasmuch as private research is not covered by NIH guidelines, immediate congressional action is called for, either to formulate regulations or to remove certain patent incentives.²⁰³

The main obstacles to the passage of genetic research legislation have been concern about violating rights of researchers,²⁰⁴ and difficulties in drafting.²⁰⁵ The reaction of the scientific com-

198. See *id.* at 2212.

199. See, e.g., *Regulation of Recombinant DNA Research: Hearings Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science and Transportation*, 95th Cong., 1st Sess. (1978); *Genetic Engineering, 1975: Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 94th Cong., 1st Sess. (1975); *Recombinant DNA Research Act of 1977: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. (1977), cited in *Diamond v. Chakrabarty*, 100 S. Ct. at 2212 n.11.

200. See, e.g., S. 2234, 96th Cong., 2d Sess. (1980) (requires annual reports of recombinant DNA research by researchers; provides for public disclosure of research, except trade secret and commercial information for which disclosure is required only in the event of an imminent hazard to the public or environment); S. 1217, 95th Cong., 1st Sess. (1976) (amended 1977) (established presidential commission with authority to issue regulations and licenses for public and private recombinant DNA research and provided for severe penalties); S. 621, 95th Cong., 1st Sess. (1976) (provided HEW should enact guidelines regulating all genetic research; required strict liability for injuries resulting from such research.); H.R. 11,192, 95th Cong., 1st Sess. (1976) (extended NIH guidelines to encompass all genetic research).

201. Berger, *supra* note 163, at 92-93; Halvorson, *DNA and the Law*, 51 S. CAL. L. REV. 1167, 1172-73 (1978).

202. 100 S. Ct. 2204 (1980).

203. See Friedman, *Health Hazards Associated with Recombinant DNA Technology: Should Congress Impose Liability without Fault?*, 51 S. CAL. L. REV. 1355, 1379 (1978).

204. See, e.g., Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1209 (1978).

205. See Berger, *supra* note 163, at 107.

munity to suggestions for regulations inhibiting scientific research has been one of fear that genetic research might be overly restricted or even banned.²⁰⁶ The researchers are aghast that anyone would interfere with academic freedom and they assert a theoretical constitutional right to conduct scientific inquiries.²⁰⁷

Minimizing Risks Through Regulation

While it is in the best interests of both the public and the scientific community to design legislation governing genetic research so as to minimize the impact on free scientific inquiry,²⁰⁸ this is not to say that regulation is unwarranted. The environmental hazards of recombinant DNA research are divisible into two categories. There is the "direct risk" of a "biohazard" involving the release of a pathogenic organism into the environment where it could infect plants and animals, causing disease or death, and there is the long-term or "indirect risk." The latter is a more speculative hazard that a recombination of DNA molecules across species lines, especially in higher life forms, would result in violation of natural barriers and cause an evolutionary disaster.²⁰⁹

In the regulation of genetic research, an even greater distinction may be drawn between these risks. We may differentiate between what has, until recently, been predominantly "pure research" in recombinant DNA and research that is intended to

206. *Id.* at 101.

207. See generally Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1209-18 (1978). Although this topic is beyond the scope of this Comment, in summary, the author bases the proposed constitutional right to research on the right to liberty and privacy of the fourteenth amendment and the right of free speech and association of the first amendment. The author points out that the Supreme Court has never decided the issue. *Id.* at 1211.

Galileo and Darwin have been cited as examples of targets of illogical public reactions to new discoveries which contradict strongly held societal beliefs. B. Davis, *Three Specters: Dangerous Products, Powers or Ideas*, in GENETICS AND THE LAW II 7 (A. Milunsky ed. 1980). The comparison of the criticism of unrestrained genetic research to the attack on Galileo and Darwin is of little value. While Galileo merely observed the heavens and Darwin contemplated unchangeable evolutionary patterns, the modern genetic engineers seek to make changes in nature. Thus the freedom of inquiry which they are seeking is not merely the freedom to observe and record, or freedom with words; it is the freedom to modify organisms that may have environmental effects deleterious to us all. Cohen, *Restriction of Research with Recombinant DNA: The Dangers of Inquiry and the Burden of Proof*, 51 S. CAL. L. REV. 1081, 1104 (1978). "Galileo is protected; Dr. Frankenstein is not." J. Robertson, *The Scientist's Right to Research and the Legitimacy of Governmental Regulation*, in GENETICS AND THE LAW II 36 (A. Milunsky ed. 1980).

208. Berger, *supra* note 163, at 107.

209. See Fletcher, *Ethics and Recombinant DNA Research*, 51 S. CAL. L. REV. 1131, 1135-36 (1978); Grobstein, *Regulation and Basic Research: Implications of Recombinant DNA*, 51 S. CAL. L. REV. 1181, 1188-89 (1978).

produce a marketable organism or by-product.²¹⁰ In the first instance, the value to the public of the "non-use-oriented" research is indirect and nonquantifiable. It consists of contributions to scientific knowledge and a greater understanding of the mechanics of biochemistry.²¹¹ Similarly, the risks to society in "non-use-oriented" research are indirect, and society may only be inadvertently affected.²¹²

It is the "use-oriented" research that will be primarily affected by the patentability of microorganisms. Because the incentives of the patent system operate primarily on the businessman and only secondarily on the scientist,²¹³ it is unlikely private industry will be interested in funding research projects that are not commercially exploitable. Thus, the patentability of microorganisms will promote private genetic research directed towards development of microorganisms for commercial introduction to the environment, or used in processes requiring much larger quantities than are needed in non-use-oriented research. Inasmuch as use-oriented research involves a greater likelihood of eventual exposure to the public, it warrants greater regulation.²¹⁴

Constitutional Aspects

Arguably, there exists a constitutionally protected right to research.²¹⁵ If that right is a fundamental right, any regulations affecting that right must satisfy the compelling state interest, substantial relation, and least restrictive alternative tests of enforceability.²¹⁶ Protecting human life and health is a compelling

210. Berger, *supra* note 163.

211. Grobstein, *supra* note 209, at 1191.

212. Berger, *supra* note 163.

213. See note 7 *supra*.

214. Grobstein, *supra* note 209, at 1196. This is not to say that non-use-oriented research may not be regulated if it involves a "direct risk" of harm to the environment, but the greatest degree of danger exists in direct risks from use-oriented research. *Id.* at 1191.

215. J. Robertson, *The Scientist's Right to Research and the Legitimacy of Governmental Regulation*, in *GENETICS AND THE LAW* II 29 (A. Milunsky ed. 1980).

216. Spece, *A Purposive Analysis of Constitutional Standards of Judicial Review and a Practical Assessment of the Constitutionality of Regulating Recombinant DNA Research*, 51 S. CAL. L. REV. 1281, 1285 (1978). The author suggests that regulations of DNA research might be subjected to the rational relation or intermediate tests of scrutiny if the right to research is determined to be less than fundamental. If the regulation can pass the compelling state interest test, however, then a fortiori it can pass these other tests. *Id.* at 1332. See also note 207 *supra*.

state interest.²¹⁷ The substantial relationship requirement will probably be interpreted to refer to both the probability and the degree of the physical danger that might be avoided by regulation. The probability and amount of harm will then be compared to the degree of intrusion on the rights of the researchers.²¹⁸

The remaining element is the regulation be the least restrictive alternative.²¹⁹ This requires that the regulation not create over-inclusive classifications to which the purpose of the enactment is not relevant, and minimize the intrusion on the rights of those to whom its purpose is relevant.²²⁰ While it appears clear that under the compelling state interest test an outright prohibition of recombinant DNA research would not be upheld,²²¹ it is not certain exactly what regulations would be sustained. This is due to the lack of adequate information regarding the magnitude and probability of danger posed by recombinant DNA research as well as uncertainty about the extent of the researcher's rights.²²² There is, however, a greater certainty of enforceability of regulations governing use-oriented research, where a direct risk of harm exists, than of regulations governing "pure" research.²²³

The problem lies in designing regulations which minimize intrusions on the right to research while adequately protecting society from the risks of research by private industry. There are several alternative approaches to congressional regulation of private research in recombinant DNA.²²⁴

Direct Regulation

First, Congress could draft legislation requiring compliance with express guidelines and providing penalties for non-compliance. While this alternative would discourage private research involving those organisms determined to be dangerous, it has the disadvantages of being overly rigid and of requiring inspection and enforcement for its effectiveness.²²⁵

Other alternatives are to apply the existing NIH Guidelines to

217. *Id.* at 1333. See *Roe v. Wade*, 410 U.S. 113 (1973).

218. Spece, *supra* note 216, at 1335.

219. *Id.* at 1340.

220. *Id.*

221. *Id.* at 1351. An outright prohibition might be upheld under the rational relation test. See note 228 *infra*.

222. *Id.*

223. Grobstein, *supra* note 209, at 1194.

224. See notes 202-05 and accompanying text, *supra*.

225. Overly technical language in the statute might be difficult for the courts and legislators to interpret, further diminishing the effectiveness of direct legislation. Berger, *supra* note 163, at 107.

private research,²²⁶ or to assign the task of designing and enforcing the regulations to an independent agency.²²⁷ While these methods have the advantage of increased flexibility, the inspection and enforcement problems remain. It is relatively certain, however, that guidelines such as the NIH Guidelines could satisfy the strict scrutiny standard of review.²²⁸

Diminishing Patent Incentives

Another approach is to diminish the incentives for private genetic research, or alternatively, to encourage voluntary compliance with the NIH Guidelines by manipulations of the patent protection. For example, Congress could expressly limit or enumerate the types of organisms which would be patentable, a method similar to that used in the Plant Patent Act.²²⁹ The regulation might provide that only organisms exempted from the NIH Guidelines could be patented.²³⁰

Prohibiting patents for inventions in hazardous fields is not a novel idea. Under the 1954 Atomic Energy Act²³¹ patents are prohibited for certain inventions related to nuclear research.²³² A similar statute could minimize the potential hazards of private genetic research by encouraging research only with the less dangerous organisms. This approach has the advantage of being only a minor intrusion on the right to research, but the disadvantage of

226. See, e.g., H.R. 11,192, *supra* note 200.

227. This method was used to assign to the Environmental Protection Agency the task of drafting the Federal Toxic Substances Control Act. See 15 U.S.C.A. §§ 2601-2629 (West Supp. 1980).

228. Spece, *supra* note 216, at 1349. It has been noted that the Supreme Court has held environmental hazards are a matter of economic regulation and not individual liberty. Thus minimal scrutiny is likely to be applied to such regulations. R. Stewart, *Legal Regulation of Environmental Risk*, in *GENETICS AND THE LAW II*, 404 (A. Milunsky ed. 1980) (citing *Duke Power Co. v. Carolina Environmental Study Group*, 438 U.S. 59 (1978)).

229. For example, patents could be limited to microorganisms derived from species not banned by the NIH Guidelines. It has been demonstrated that there is an extraordinary correlation between mutagenic potency and carcinogenicity to man. Thus research on mutagens and carcinogens should be restricted. S. Lederberg, *Public Control of Genetic Research*, in *GENETICS AND THE LAW II*, 42 (A. Milunsky ed. 1980). See Note, *Living Matter Found to be Patentable*: In re Chakrabarty, 11 CONN. L. REV. 311 (1979).

230. See NIH Guidelines, *supra* note 85, at 60,130.

231. Act of August 30, 1954, ch. 13, 68 Stat. 943 (codified at 42 U.S.C. § 2181 (1976)).

232. See Note, *Ownership of Living Inventions*—In re Bergy, 29 DE PAUL L. REV. 205, 233 n.124 (1979).

depending on the assumption that private industry will only conduct research with organisms which they eventually intend to patent.²³³

As an alternative, the regulation might provide that no patents for microorganisms or processes related to recombinant DNA research will be issued to any research firm or institution unless NIH Guidelines are followed.²³⁴ This has both the advantage and disadvantage of relying on voluntary compliance with the NIH Guidelines.²³⁵

There are several major advantages to patent incentive manipulation. The intrusion on academic freedom would be minimal because non-use-oriented research would be unaffected. Congress could avoid problems in drafting technical regulatory legislation. The fiscal impact would be minimal because no enforcement would be necessary. The disadvantage of incentive based regulations is that rather than comply voluntarily with the guidelines, or rather than conduct research only with patentable organisms, the private research firms might resort to trade secrecy. Unless the new microorganism or process could be discovered by reverse engineering, the public could be denied valuable information concerning the invention.²³⁶ Congress could, however, require prior public disclosure of all private genetic research so as to assure public safety.²³⁷ Even though it might preclude patentability, such a measure could be necessary until the dangers of genetic research are eliminated or disproved.²³⁸

Testing for Safety

Rather than require disclosure, Congress could require the organism be proven safe before it is mass produced or exposed to

233. See text accompanying notes 213-14 *supra*.

234. This is similar to the provision of S. 621, note 200 *supra*, except that S. 621 required all applicable guidelines be followed and at present there are no guidelines applicable to private genetic research. See notes 171, 179-84 and accompanying text *supra*.

235. The advantage being that the intrusion on the rights of the researchers is minimized. The disadvantage is that researchers only need comply if they intend to seek patents. The regulation would have to provide for a requirement that the NIH Guidelines be followed for a certain period prior to the patent application.

236. "Reverse engineering" is the technique of analyzing a commercially available product to determine the process involved in its production. While it is an accepted method for discovering trade secrets, it is virtually impossible to implement with genetically engineered organisms. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974); Gutttag, *supra* note 24, at 277; Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101*; *Parker v. Bergy* (*Parker v. Chakrabarty*), 15 NEW ENG. L. REV. 379, 404-05 (1980).

237. Note, *Living Matter Found to be Patentable*: In re Chakrabarty, 11 CONN. L. REV. 311, 326 n.58 (1979).

238. *Id.*

the public.²³⁹ When a technology is potentially dangerous, or its safety even questionable, it might legitimately be prohibited or regulated until the researcher can demonstrate that no unreasonable danger exists.²⁴⁰ Although this method would serve the purpose of protecting the public from exposure to a dangerous organism, it would do so only after the research is complete and the organism is ready for the market. It would have no effect on the adoption of proper laboratory techniques, nor would it discourage research with dangerous organisms not intended to be marketed.²⁴¹

Liability Insurance/Strict Liability

An approach that has been suggested for general applicability to genetic research²⁴² is the enactment of a statute similar to the Price-Anderson Act.²⁴³ Congress would require all private genetic research firms carry a certain minimum amount of liability insurance and be held strictly liable for injuries caused by their research.²⁴⁴ This principle could also be applied as a condition precedent only to those firms seeking patent protection. The main defect of such an insurance approach is that while it provides relief to victims it does not provide a complete remedy nor prevent what may be irreparable environmental harm caused by a biohazard. It does, however, provide a general deterrent to dangerous research through a market mechanism requiring little governmental intervention.²⁴⁵

CONCLUSION

The task of balancing the competing costs and benefits of ge-

239. This could be done by analogizing to the Toxic Substances Act, 15 U.S.C.A. §§ 2601-2629 (West Supp. 1980), and the National Environmental Policy Act, 42 U.S.C. §§ 4321-4347 (1976). Berger, *supra* note 163, at 100.

240. *Id.* Accord Cohen, *Restriction of Research with Recombinant DNA: The Dangers of Inquiry and the Burden of Proof*, 51 S. CAL. L. REV. 1081 (1978); Hutt, *supra* note 179, at 1439.

241. For example, an organism used in a process that produces a marketable product.

242. See S. 621, note 200 *supra*.

243. Pub. L. No. 85-256, § 4, 71 Stat. 576 (1957) (codified at 42 U.S.C. § 2210 (1976)).

244. Friedman, *supra* note 203, at 1377.

245. C. Damme, *Controlling Environmental Mutagens: Through Market Incentives or State Action?*, in GENETICS AND THE LAW II 382 (A. Milunsky ed. 1980).

netic research to society is a complex one, requiring detailed examination and carefully constructed legislation. The difficulty of the situation is exacerbated by the need for immediate action to mitigate the dangers inherent in unregulated, private genetic research. While the prohibition of all genetic research is too harsh a protective measure, a certain degree of coercion may be necessary to ensure private industry cooperation with government guidelines. As the Supreme Court noted in *Diamond v. Chakrabarty*,²⁴⁶ merely denying patents probably will not forestall private genetic research.²⁴⁷ Yet it is equally clear that extending patents to products of genetic research will not enhance public safety.

The courts are not without the means to deny patent incentives to private genetic research. Patents on microorganisms could be refused based on the ambiguity of the relationship of the Plant Patent Act and the patent statutes. The microorganism could be characterized as embodying a phenomenon of nature, even if the phenomenon is not displayed in nature.²⁴⁸ The patent could also be denied on the basis of the preemption doctrine. Until such time as legislation is drafted by Congress, the courts should refrain from encouraging unregulated, private research in recombinant genetics, keeping in mind the threat such research poses to society.

While none of the regulations suggested would provide a perfect solution to the problem created by the Supreme Court's decision to encourage unregulated genetic research, they would provide a measure of safety during what must be a short period before Congress acts to provide more comprehensive legislation. Congress may decide not to extend patent protection to the products of genetic research. If so, as the Supreme Court has suggested, the research would continue through the encouragement of the profit motive. Thus merely denying patent protection is insufficient. The most effective solution to the problem would be a combination of the regulatory and patent incentive approaches. Congress should create an agency responsible for the development of regulations governing genetic research, or allocate such power to the Environmental Protection Agency, and provide that agency with the funds and power to enforce its guidelines. As part of this scheme, to penalize noncompliance, no patents should issue to firms or institutions that fail to comply with the regula-

246. *Diamond v. Chakrabarty*, 100 S. Ct. 2204, 2204 (1980).

247. *Supra* notes 90-91.

248. *Supra* note 33.

tions. Until such regulation can be enacted, Congress should act to apply the NIH Guidelines to all genetic research.

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